UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
GREENBELT DIVISION

MALLINCKRODT INC., Plaintiff, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	)	C.A. No. 8:14-cv-03607-DKC

PLAINTIFF'S OPPOSITION TO MOTION TO DISMISS AND MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Court should deny the government's motion to dismiss, because this case is ripe for review, and Mallinckrodt has properly pleaded its claims for relief. The Court then should grant Mallinckrodt's cross-motion for summary judgment on the merits of this case. There is no reason to delay entering summary judgment for Mallinckrodt. In general, "when a party seeks review of agency action under the [Administrative Procedure Act ("APA")], the district judge sits as an appellate tribunal. The 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In this case, the Court is positioned to rule on the merits now as a matter of law, because there is no genuine dispute of material fact. Fed. R. Civ. P. 56(a).[1]

In addition, the fact that the government has not produced the full administrative record does not preclude summary judgment on Mallinckrodt's APA claims.[2] Although

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[1] There typically is no genuine dispute of material fact in connection with APA claims, because the pertinent facts generally are those contained within the administrative record. *See, e.g., Dow Agrosciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 467 (4th Cir. 2013). The administrative record is the record made before the agency at the time the agency acted and includes both "the facts presented to the agency" and the "reasons given by the agency for taking the action." *Id*. In addition, Mallinckrodt introduced other facts into the Court's record by filing exhibits and declarations in connection with the motion for temporary restraining order, to address the four-factor test applicable to that motion. The government has not introduced any contrary evidence into the record that would create a genuine dispute of material fact.

[2] Mallinckrodt has made every effort to convince the government to give the Court time to consider ordering production of the full administrative record before this Memorandum was filed. *See* Mot. to Require Produc. of Admin. R., ECF No. 31, at 1

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the government ordinarily produces the full administrative record prior to summary adjudication of APA claims, the administrative record is unnecessary to resolve most of Mallinckrodt's APA claims, which address pure questions of law unrelated to that record. *See, e.g., Am. Banker's Ass'n v. Nat'l Credit Union Admin.*, 271 F.3d 262, 266-67 (D.C. Cir. 2001) (no need for administrative record where challenge to rule could be "resolved with nothing more than the statute and its legislative history") (citing *Sierra Club v. U.S. Fish & Wildlife Serv.*, 245 F.3d 434, 440 n.37 (5th Cir. 2001) ("Although the administrative record for the regulation is not before this Court, that is of no moment. Our review is limited to interpreting the extent to which the regulation is consistent with the statute — a task which we are competent to perform without the administrative record.")). For its remaining APA claims, Mallinckrodt has had access to some of the administrative record, because parts are public, and FDA also has produced the memorandum memorializing the reasons for the reclassification action being challenged. *See infra* at 38-46. These portions of the administrative record provide a sufficient factual basis for summary judgment at this time, so there is no reason to postpone a final decision on the merits. *See* Fed. R. Civ. P. 56(b) (party may file summary judgment

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n.1, 3 n.3. The government's decision to file its motion to dismiss more than three weeks early has preempted that effort. If the Court grants Mallinckrodt's motion to produce the full administrative record, and the administrative record contains new materials pertinent to Mallinckrodt's motion for summary judgment, Mallinckrodt likely will seek leave to file a supplemental brief addressing the new materials.

motion "at any time until 30 days after the close of all discovery").

STATUTORY AND REGULATORY BACKGROUND

The regulatory regime governing FDA's authority for premarket approval of drugs is set forth in the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq*. The FFDCA applies separate requirements for the approval of new brand-name drugs (also known as innovator drugs) and generic drugs. Although the process of approving brand-name drugs is typically more burdensome and time-consuming, prior to approval of both types of drugs, FDA must conduct an extensive review to determine that the drug is safe and effective. Based on this review, as described below, FDA approved Mallinckrodt's methylphenidate ER as a safe and effective substitute for the brand-name drug Concerta®.

New Drug Approvals

In order to market and sell a brand-name drug, a company must submit a New Drug Application ("NDA"). As set forth in 21 U.S.C. § 355, an NDA must outline and explain the drug's ingredients, the results of clinical tests, the results of animal studies, how the drug behaves in the body, and how the drug is manufactured, processed, and packaged. Before approving an NDA, FDA must evaluate numerous statutorily-defined criteria, including whether the drug is safe and effective in its proposed use. *See* 21 U.S.C. § 355 *et seq*.

In order to market and sell a generic drug, a company must submit an Abbreviated New Drug Application ("ANDA"). As set forth in 21 U.S.C. § 355(j), an ANDA

applicant may obtain FDA approval of a drug that is the "same" as a previously approved brand-name drug without conducting the full battery of clinical and non-clinical studies that are required for an NDA. *See generally* 21 U.S.C. § 355(j). An ANDA applicant is allowed to rely upon a prior FDA finding of safety and efficacy for the approved brand-name drug that is referenced by the ANDA applicant, provided that the proposed generic drug is the "same" as the approved brand-name drug with regard to active ingredients, dosage form, route of administration, strength, and labeling. *Id*. § 355(j)(2)(A)(i), (ii), (iii), and (v). In addition, before approving an ANDA, FDA is required to determine that the proposed generic drug is "bioequivalent" to the referenced brand-name drug. *See* 21 U.S.C. § 355(j)(4)(F); 21 C.F.R. § 314.127(a)(6)(i). In general, a generic drug is "bioequivalent" to the corresponding brand-name drug if, in single-dose or multiple dose clinical studies, the "rate and extent of absorption" of the two drugs are not significantly different. *See* 21 U.S.C. § 355(j)(8)(B).

The Orange Book

The FFDCA mandates that FDA publish a list all drugs that have been approved, *see* 21 U.S.C. § 355(j)(7)(A)(i)(I)-(III), and FDA has elected to fulfill this statutory duty by publishing the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

Among other things, the Orange Book contains FDA's evaluations of "therapeutic equivalence." In sum and substance, FDA defines therapeutic equivalence as a combination of two elements: (i) "pharmaceutical equivalence" (*e.g.*, having the same

active ingredient, dosage form, route of administration); and (ii) "bioequivalence" (defined *supra*). Ex. 1 at vi-viii.[3]

FDA lists its therapeutic equivalence ratings in the Orange Book in the form of two-letter codes — *e.g.*, AA, AB, BP, BX. According to FDA, these therapeutic evaluations "have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs." *Id.* at iv. The Orange Book provides an explanation of the specific therapeutic equivalence codes. Relevant here, FDA uses various "A codes" and "B codes" to designate whether the drug product is considered by FDA to be therapeutically equivalent to another listed drug. Those drugs considered by FDA to be therapeutically equivalent are listed with a two-letter code beginning with "A." Those drugs considered by FDA not to be therapeutically equivalent are listed with a two-letter code beginning with "B." *Id*. at xiii.

The Orange Book therapeutic equivalence ratings are commonly used by pharmacists to determine whether a generic drug may be dispensed to a patient who has been prescribed the brand-name version of the same drug. FDA states in the Orange

[3] Mallinckrodt incorporates by reference herein the exhibits, and original and supplemental declarations of Walt Kaczmarek and Mario Saltarelli (and exhibits thereto), that Mallinckrodt filed in connection with its motion for temporary restraining order. Mallinckrodt has cited to those exhibits and declarations in this Memorandum without refiling them with the Court.

Book that therapeutically equivalent drugs "can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product." Ex. 1 at vii. As a result, FDA's therapeutic equivalence ratings have become the recognized authoritative standard for determining whether a pharmacist may substitute one drug for another, and pharmacists typically use generic drugs to fill prescriptions for brand-name drugs (such as Concerta®) only if the generic version is classified in the Orange Book as automatically substitutable for the brand drug.

Withdrawal of Drugs From the Market

Once an ANDA is approved, FDA is authorized to take a drug off the market through a statutorily-mandated process, as defined in 21 U.S.C. § 355(e). Section 355(e) requires "due notice and opportunity for hearing to the applicant."

There is no statutory or regulatory mechanism by which FDA can take a generic drug off the market without providing the applicant notice and an opportunity for a hearing. In fact, FDA is required by law to provide the applicant notice and an opportunity for a hearing even in those instances in which FDA believes there is an imminent health risk. The statute requires FDA to allow the applicant an opportunity for an "expedited hearing" in the event the Secretary finds there is "an imminent hazard to the public health." 21 U.S.C. § 355(e). In a press release, FDA has expressly acknowledged that no such safety risk is at issue here. Decl. of Mario Saltarelli ("Saltarelli Decl.") (filed under seal), Ex. B.

STATEMENT OF FACTS

This case concerns an important drug product, methylphenidate ER, a generic drug marketed and sold by Mallinckrodt as an alternative to the brand-name drug Concerta®. Mallinckrodt's product is used to treat patients suffering from attention-deficit hyperactivity disorder ("ADHD"). *See* Saltarelli Decl. ¶ 6.

FDA's Approval and Determination of Therapeutic Equivalence

FDA approved Mallinckrodt's methylphenidate ER on December 28, 2012. Saltarelli Decl. ¶ 11. Based on scientific studies and data reviewed and analyzed by FDA at the time, none of which have changed, FDA concluded the product was "therapeutically equivalent" to Concerta®. *Id.* As a result, FDA listed the methylphenidate ER tablets as "AB"-rated in the Orange Book, signifying FDA's considered conclusion that Mallinckrodt's "application contains scientific evidence establishing through *in vivo* and/or *in vitro* studies the bioequivalence of the product to a selected reference product." *See* Ex. 1 at xiv.

Mallinckrodt's Successful Marketing and Sale of Methylphenidate ER

Since being approved, Mallinckrodt's product has proven to be an important, cost-effective alternative to the brand drug, as well as a successful and safe product. More than 88 million doses of the drug have been prescribed, and it has been dispensed in tens of thousands of pharmacies. Saltarelli Decl. ¶¶ 13-16. Mallinckrodt has successfully marketed methylphenidate ER in 27 mg, 36 mg, and 54 mg tablets. Until recently, all three dosage strengths have had a therapeutic equivalence rating of AB in the Orange

Book, making them automatically substitutable for the same dosage strengths of Concerta® at the pharmacy level. Decl. of Walt Kaczmarek ("Kaczmarek Decl.") ¶¶ 5, 20-21, 25 (filed under seal); Saltarelli Decl. ¶ 18.

Methylphenidate ER was Mallinckrodt's most profitable product in fiscal year 2014 — not only for generic drugs but for all products and across all business units of the company. Kaczmarek Decl. ¶ 26. For the fiscal year ended September 30, 2014, Mallinckrodt generated more than $209 million in sales of methylphenidate ER tablets. *Id*. ¶ 27. In terms of sales and profitability, methylphenidate ER has been critical to Mallinckrodt's business.

Methylphenidate ER also has been critical to the patient community. There currently is a supply shortage in the methylphenidate ER market. FDA's Drug Shortage Program website lists Methylphenidate Hydrochloride ER Capsules/Tablets as "Currently in Shortage." *Id*. ¶ 52, Ex. B.

FDA's Abrupt Reversal and Reclassification Action

On November 12, 2014, after Mallinckrodt's product had been successfully on the market for almost two years, and without any warning, FDA informed Mallinckrodt during a teleconference that the agency planned to take an immediate action reclassifying Mallinckrodt's methylphenidate ER tablets from an AB rating to a BX rating in the Orange Book, denoting the agency's apparent conclusion that the drug is not automatically substitutable for the brand-name drug. Saltarelli Decl. ¶ 18; Kaczmarek Decl. ¶ 20. An FDA official expressly confirmed that the reclassification was a "final

agency action." Saltarelli Decl. ¶ 20.

During the November 12, 2014 teleconference, FDA officials told Mallinckrodt that the agency's reclassification action was based on the application of a new "draft guidance" document regarding bioequivalence for methylphenidate hydrochloride products. Saltarelli Decl. ¶ 19. FDA took the position that the "draft guidance" applied even though FDA had published the "draft guidance" less than one week earlier, on November 6, 2014, and even though the "draft guidance" remained open for comment through January 5, 2015. *Id*.

In response to Mallinckrodt's queries, an FDA official stated that the agency would provide Mallinckrodt with "compelling" supporting data, including case report forms, and specifically referred to a detailed report of over 100 pages supporting FDA's decision. Even though Mallinckrodt has made additional requests for this alleged data, the only written rationale that the agency has provided for its action is a 15-page summary memorandum. Saltarelli Decl. ¶¶ 21, 25, 26. That memorandum contains numerous factual inaccuracies, faulty assumptions, and otherwise flawed analyses. *Id.* ¶¶ 28-50.

Both during and after the phone call with FDA, Mallinckrodt representatives objected — orally and in writing — to FDA's surprise reclassification action as not supported by appropriate evidence and not consistent with patients' best interests. Mallinckrodt also requested an opportunity to address any concerns identified by FDA,

and to engage in a dialogue with FDA. FDA, however, has not provided any opportunity for Mallinckrodt to be heard since announcing FDA's reclassification action. Saltarelli Decl. ¶¶ 21-22.

On November 13, 2014, one day after first announcing its surprise action, FDA formally reclassified Mallinckrodt's methylphenidate ER tablets to a BX rating in the Orange Book. Ex. 2; Saltarelli Decl. ¶ 23. The same day, FDA issued a press release and a separate public document containing "Questions and Answers" about the product and action. Saltarelli Decl. ¶ 24. In these public pronouncements, FDA stated that it had "concerns about whether or not" Mallinckrodt's product is "therapeutically equivalent to the brand name drug" for "some patients." *Id.*, Ex. B. The agency emphasized that "FDA has not identified any serious safety concerns" with the product. *Id.* FDA claimed that it had based its decision on some number of "adverse event reports," but FDA acknowledged that "the total number of lack of effect reports" was "very small compared to overall usage of the product." *Id.*, Ex. C.

The reclassification action triggered immediate and substantial harmful effects on Mallinckrodt. This action followed.

ARGUMENT

I. THE COURT SHOULD DENY THE GOVERNMENT'S MOTION TO DISMISS

A. The Court Should Deny the Motion to Dismiss Under Rule 12(b)(1) Because the Case is Ripe for Review

1. The Government's Ripeness Defense is its Only Jurisdictional Defense

In evaluating the motion to dismiss, the Court should first reject the government's attempt to blur the distinction between its ripeness defense (which is jurisdictional) and its "final agency action" defense (which is not). *See* Mem. in Supp. of Def.'s Mot. to Dismiss ("Gov't Br.") at 1 (asserting that the case is not ripe "in large part" because there allegedly is no "final agency action").

Ripeness is a question of justiciability relating to whether the parties have a "case or controversy" cognizable under Article III of the Constitution. *See, e.g., Cooksey v. Futrell*, 721 F.3d 226, 239-40 (4th Cir. 2013). By contrast, the "final agency action" defense is a non-jurisdictional defense addressing whether the APA provides a statutory remedy for a plaintiff's injury. The APA provides a remedy only for "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. If an agency action is not a "final agency action" within the meaning of the APA, that statute provides no remedy. Therefore, as the government concedes, the "final agency action" defense is properly raised under Rule 12(b)(6), not Rule 12(b)(1). Gov't Br. at 16. The absence of a statutory remedy under the APA does not mean the court lacks jurisdiction. *See, e.g.*,

Cohen v. United States, 650 F.3d 717, 723 (D.C. Cir. 2011). It is well established that the APA is not a jurisdictional statute. *Califano v. Sanders*, 430 U.S. 99, 107 (1977); *Vietnam Veterans of Am. v. Shinseki*, 599 F.3d 654, 661 (D.C. Cir. 2010) ("We think the proposition that the review provisions of the APA are not jurisdictional is now firmly established.")[4]

As set forth below, the Court should reject the government's ripeness defense under Rule 12(b)(1). The Court then should reject the government's "final agency action" defense as to all of the APA claims (i.e. Counts I and III through V) under Rule 12(b)(6). Finally, the Court should hold that Mallinckrodt properly pleaded the elements of its due process claims (Counts I and II) under Rule 12(b)(6).[5]

2. <u>The Parties' Dispute is a Ripe "Case or Controversy"</u>

In the context of this case, the ripeness question is fundamentally affected by a

[4] Regardless of whether there is a final agency action, 28 U.S.C. § 1331 grants the Court jurisdiction to hear any claim arising under a federal statute or the federal Constitution. In addition, Congress has waived the government's (jurisdictional) sovereign immunity defense for actions against federal agencies that do not seek money damages. This waiver of sovereign immunity empowers the Court to adjudicate claims against federal agencies that fall outside the definition of an APA "final agency action." *See, e.g.*, *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996) (the "waiver of sovereign immunity applies to any suit whether under the APA or not"); *Trudeau v. FTC*, 456 F.3d 178, 187 (D.C. Cir. 2006) (waiver of sovereign immunity applies regardless of whether there is a "final agency action").

[5] Count I pleads a due process claim under the APA and Count II pleads a due process claim directly under the Constitution.

bedrock principle of administrative law — the "basic presumption of judicial review" that applies to all federal agency actions. *See, e.g.*, *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967). The presumption that FDA's actions are judicially reviewable is so fundamental that it even predates the APA. *Id*. at 142 (discussing pre-APA judicial review "in the food and drug area"). The government has not overcome the presumption that there is a justiciable "case or controversy" here.

a. The Case or Controversy Arises From FDA's Determination That Mallinckrodt's Drug is Not Therapeutically Equivalent to Concerta®

The case or controversy at issue arises from FDA's determination — harmful to Mallinckrodt — that Mallinckrodt's methylphenidate ER tablets are not therapeutically equivalent to Concerta®. FDA effectuated that determination by reclassifying the drug from "AB" to "BX" in the Orange Book. As the Orange Book specifies, the "B" rating denotes a drug that "FDA, at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products." Ex. 1 at xiii (emphasis in original); *see also id*. at xvii. The prior "A" rating denoted a drug that "FDA consider[ed] to be therapeutically equivalent to other pharmaceutically equivalent products." *Id*. at xiii (emphasis in original).

The government tries to minimize the significance of the "B" rating by sidestepping FDA' bottom-line conclusion — that FDA considers "B" drugs "not to be therapeutically equivalent" — and changing the subject to the *reason* that FDA considers them not to be therapeutically equivalent. (FDA's stated reason is that there is not

adequate evidence of bioequivalence.) Gov't Br. at 4. The fact that FDA has made a therapeutic equivalence determination based on a lack of evidence plainly does not mean (as the government suggests) that FDA has made *no* determination. Just as this Court enters a binding judgment on the merits, based on lack of evidence, when a plaintiff cannot meet its evidentiary burden of proof, FDA makes a definitive determination that there is no therapeutic equivalence (through a "B" rating) when the agency concludes there is inadequate evidence supporting equivalence. As explained more fully *infra* at 31-34, FDA's affirmative determination that a drug is not therapeutically equivalent (based on lack of evidence) is directly analogous to an FDA decision withdrawing an ANDA for lack of effectiveness (which also is based on lack of evidence). FDA only has statutory authority to withdraw an ANDA for lack of effectiveness if "there is a *lack of substantial evidence* that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 355(e)(3) (emphasis added). The government concedes that an ANDA withdrawal decision is judicially reviewable even though it is based on lack of evidence. Gov't Br. at 10-12. The reclassification action is no different.[6]

[6] In addition, the fact that the reclassification action relied on lack of evidence does not mean, as the government asserts, that the agency is mid-way through a scientific evaluation. There is no basis for believing that FDA has not completed its evaluation or will conduct any additional evaluation of the current evidence before the agency. *See infra* at 20-22.

FDA's reclassification action has concrete and harmful effects on Mallinckrodt under both federal and state law, confirming that there is a ripe case or controversy. The reclassification action means that (depending on the jurisdiction) it is either unlawful or unacceptably risky for pharmacists to fill a prescription by substituting Mallinckrodt's generic for the brand-name drug Concerta®. In 31 states (including Maryland) and the District of Columbia, it is *unlawful* for a pharmacist to fill a prescription with a generic drug (by substituting it for the corresponding brand-name drug) if the generic is rated "B" (*i.e.*, not therapeutically equivalent) in the Orange Book. *See, e.g.*, Md. Code Ann., Health Occ. § 12-504 (generic substitution is only permissible if "the substitution is recognized in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations."); *see also* Ex. 3 (chart setting forth the generic substitution laws for all fifty states and the District of Columbia). Accordingly, on November 13 — the date FDA amended the Orange Book to reflect the BX classification — it immediately became *per se* unlawful for pharmacists to substitute Mallinckrodt's generic when filling prescriptions for Concerta® in those 31 states and the District of Columbia.

In another fourteen states, the statutes and regulations governing generic substitutions do not expressly refer to the Orange Book but nonetheless use the Orange Book's terms of art (including the terms "therapeutic equivalence" and "pharmaceutical

equivalence") when addressing generic substitution. *See* Ex. 3.[7] In these states, the legal duty guiding pharmacists' generic substitutions is the duty to abide by applicable professional standards. *See, e.g.*, Ga. Code. Ann. § 26-4-81 ("Substitutions . . . are authorized for the express purpose of making available to the consumer the lowest retail priced drug product which is in stock and which is, in the pharmacist's reasonable professional opinion, both therapeutically equivalent and pharmaceutically equivalent."). The Orange Book is — and is intended by FDA to be — the most authoritative standard that pharmacists rely on to guide their professional judgment regarding generic substitution.[8]

In these fourteen states (as well in as the remaining five states that have statutory terminology less specifically tied to the Orange Book terms of art), pharmacists' duty to

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[7] FDA refers to these terms as its "terms of art" and has taken the position in prior litigation that it has "an interest in insuring that only one definition of FDA terms of art, such as 'therapeutically equivalent' and 'generic,' is used in the context of drug approval, acceptance and use." *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 866 (W.D. Tex. 2001).

[8] The Orange Book is only the most recent effort by the FDA to provide uniform therapeutic equivalence standards for the states. FDA has been providing uniform standards for over thirty years. *See, e.g.*, 45 Fed. Reg. 72,582, 72,582 (Oct. 31, 1980) (stating that the list of therapeutically equivalent drugs "was prepared in response to requests from State health agencies for assistance in administering their drug product selection laws"). On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act, which requires the FDA to make publicly available a list of approved drug products with monthly supplements. The Orange Book is published to satisfy this requirement. Ex. 1 at v.

abide by professional standards is enforced through state regulations and tort law. These state laws compel pharmacists to follow the Orange Book classification, because it is the authoritative professional standard. The regulatory effect of the Orange Book classification is the same whether the pharmacist's professional duty arises under state statute or regulation, state tort law, or both. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008) (equating regulatory effect of state regulatory law and state tort duties because both change private parties' conduct). Regardless of the details of these states' regulatory regimes, pharmacists will seek to avoid liability by refusing to substitute Mallinckrodt's "BX" generic when filling prescriptions written for Concerta®.

In addition, the reclassification action has imposed additional harm on Mallinckrodt under federal regulations that restrict substitution of "B"-rated generic drugs under federal entitlement programs. For example, the Department of Defense's Military Health System provides a prescription drug health care benefit to active duty service members, retired service members, and their dependents. That benefit (called TRICARE) covers prescription drug costs at military hospitals and other treatment facilities, a TRICARE mail order pharmacy, and private retail pharmacies. 32 C.F.R. § 199.21(h)(1). The Department of Defense's regulations require that (with an exception not applicable here) generic drugs rated "A" in the Orange Book must be substituted for brand name drugs at the military hospitals and other treatment facilities, the TRICARE mail order pharmacy, and retail pharmacies. *See* 32 C.F.R. § 199.21(j)(2) ("[t]he

pharmacy benefits program generally requires mandatory substitution of generic drugs listed with an 'A' rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the FDA"). FDA's reclassification action harms Mallinckrodt because its "B"-rated drug is no longer automatically substituted when prescriptions are filled for this substantial population of beneficiaries.

FDA's reclassification action also harms Mallinckrodt under the Military Health System's copayment regulations by eliminating an incentive to buy Mallinckrodt's drug. If a beneficiary purchases a prescription at the TRICARE mail order pharmacy or at a retail pharmacy, the Department of Defense provides insurance coverage for the purchase (minus a co-payment that the beneficiary pays the pharmacy). 32 C.F.R. § 199.21(i). The copayment for "A"-rated generic drugs is substantially discounted compared to the copayment for a name-brand drug, incentivizing patients to seek the generic. *See id.* § 199.21(i); *id*. § 199.21(j)(1) ("Pharmaceutical agents will be designated as generics [subject to the generic cost-share rate] when listed with an "A" rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the Food and Drug Administration, or any successor to such reference."). Because of FDA's reclassification action, that incentive no longer applies to Mallinckrodt's "B"-rated drug.

The Medicare Part D prescription drug insurance program similarly incorporates Orange Book ratings. For example, the program's regulations define "therapeutically

equivalent" drugs as those rated as such in the Orange Book (i.e. "A"-rated drugs). 42 C.F.R. § 423.100 ("*Therapeutically equivalent* refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations.'"). Among other things, the program's regulations require disclosure, to Medicare beneficiaries, of the cost difference between a brand-name drug and its less expensive "A"-rated generic counterpart, in order to incentivize use of the "A"-rated drug. *id.* §§ 423.132(a), 403.806(d)(8). Because of FDA's reclassification action, that incentive no longer applies to Mallinckrodt's "B"-rated drug.

b. <u>The Issues are Fit for Judicial Decision</u>

This case is ripe under the two-factor test established in the applicable case law. The first factor that the Court must assess is "'the fitness of the issues for judicial decision.'" *Cooksey*, 721 F.3d at 240 (quoting *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003)). The "fitness" prong generally addresses "'whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final.'" *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1308 (D.C. Cir. 2010) (citation omitted). The issues presented here — matters of constitutional right, statutory interpretation, arbitrary and capricious agency action and procedural correctness arising from FDA's reclassification action — obviously are purely legal. As explained *infra* in Section II of this Memorandum, summary judgment for Mallinckrodt is warranted for all of its claims,

starkly demonstrating that the issues are purely legal and that no more concrete setting is necessary for the Court to adjudicate the claims.

Furthermore, FDA itself has conceded that its reclassification action is final. Saltarelli Decl. ¶ 20. And for good reason. The action is not subject to additional review at a higher level within the agency before being finalized and effectuated — FDA's reclassification action was complete when published in the Orange Book on November 13, 2014. Thus, this is *not* a case that lacks ripeness on the ground that there is a possibility — which is "real" and "not theoretical" — that "further consideration will actually occur before [implementation]." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 735 (1998).

In addition, as an action that was complete on November 13, the action is not contingent on future events. *See Texas v. United States*, 523 U.S. 296, 300 (1998) (claim not ripe if it "rests upon 'contingent future events that may not occur as anticipated, or indeed may not occur at all'" (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580-81 (1985)); *see also Devia v. NRC*, 492 F.3d 421, 424 (D.C. Cir. 2007) (claim not ripe if agency decision "may never have 'its effects felt in a concrete way by the challenging parties'" (quoting *Abbott Labs*, 387 U.S. at 148-49)).

Finally, there is no plausible basis for believing that FDA will change its position on the record before it; that is why FDA has requested Mallinckrodt to withdraw its ANDA formally. *See* Gov't Br. at 7, 10-11. Mallinckrodt's claims are ripe, because "an

about-face" by FDA "seems extraordinarily unlikely" and there is only a "mere theoretical possibility that [the] agency could alter its views." *Teva*, 595 F.3d at 1309.[9]

Given that the reclassification action is complete, and that FDA has requested Mallinckrodt to withdraw its ANDA, the government cannot support its self-serving assertion that FDA's "review of Mallinckrodt's product is ongoing." Gov't Br. at 11. All that FDA has done is to give Mallinckrodt the option of generating new data that the company could submit to FDA in the future, as a basis for requesting FDA to reconsider the reclassification based on different evidence. *Id.* at 10-12. It is this option — and not the final reclassification action effectuated on November 13 — that is wholly speculative and contingent on unknown future events. Given that FDA's data invitation is based on an underlying standard that lacks an adequate scientific basis (*see infra* at 46 n.25), there is a substantial question whether generation of such data would be productive. And even if such data were generated and submitted to FDA, there is only a speculative possibility that FDA would change the Orange Book "BX" classification. This wholly theoretical

[9] The government is simply wrong when it asserts that the finality determination under the ripeness doctrine is the same as the two-part test for "final agency action" under the APA (described *infra* at 25-26). Gov't Br. at 9. An action may be sufficiently final for a claim to be ripe even if the action does not meet the two-part APA test. *Trudeau*, 456 F.3d at 191-97 (reviewing pleading sufficiency of First Amendment claim, in the absence of "final agency action," under Fed. R. Civ. P. 12(b)(6)); *see also Chamber of Commerce*, 74 F.3d at 1328, 1332 (holding that "lack of a statutory cause of action" under APA does not bar judicial review and reviewing challenge to government action on the merits).

possibility of agency reconsideration, based on unknown future data that may never be generated or submitted for review, does not render Mallinckrodt's challenge to the reclassification action unripe. Even under the statutory APA finality standard, the "mere possibility that an agency might reconsider" does "not suffice to make an otherwise final agency action nonfinal." *Sackett v. EPA*, 132 S. Ct. 1367, 1372 (2012); *see also Nat'l Envtl. Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1006 (D.C. Cir. 2014) ("An agency action may be final even if the agency's position is 'subject to change' in the future.") (citation omitted).

c. Withholding Court Consideration Would Impose Hardship On Mallinckrodt

The second factor for the Court to consider under the ripeness doctrine is the "'hardship to the parties of withholding court consideration.'" *Cooksey*, 721 F.3d at 240 (quoting *Nat'l Park Hospitality Ass'n*, 538 U.S. at 808). The "hardship" prong is "not a *sine qua non* of ripeness" and is "'largely irrelevant in cases . . . in which neither the agency nor the court have a significant interest in postponing review.'" *Teva Pharms.*, 595 F.3d at 1310 (quoting *Electric Power Supply Ass'n v. FERC*, 391 F.3d 1255, 1263 (D.C. Cir. 2004)). Mallinckrodt has easily met the "hardship" prong simply because it suffers the consequences of "allegedly unlawful administrative procedures." *Cohen*, 650 F.3d at 736.

Furthermore, postponing judicial review would exacerbate the already-massive

economic harm that Mallinckrodt previously has documented for the Court.[10] While significant harm already has been suffered, without this Court's intervention, Mallinckrodt will continue to suffer additional and continuing economic harm as the remainder of its methylphenidate ER market disappears. The hardship from withholding Court consideration confirms that Mallinckrodt's claims are ripe.[11]

B. The Court Should Deny the Motion to Dismiss Under Rule 12(b)(6)

A Rule 12(b)(6) motion challenges the legal sufficiency of a complaint, as governed by Fed. R. Civ. P. 8. *F.T.C. v. Innovative Mktg., Inc*., 654 F. Supp. 2d 378, 384 (D. Md. 2009). The standard of review for a Rule 12(b)(6) motion is "relatively lenient" (*Kensington Physical Therapy, Inc. v. Jackson Therapy Partners, LLC*, 880 F. Supp. 2d 689, 692 (D. Md. 2012)), and requires courts to "construe the pleading requirements prescribed by [Fed. R. Civ. P.] 8 liberally." *F.T.C.*, 654 F. Supp. 2d at 384. The Court "must accept the factual allegations of the complaint as true" (*GE Inv. Private Placement Partners II v. Parker*, 247 F.3d 543, 548 (4th Cir. 2001) (citing *Mylan Labs., Inc. v.*

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[10] Mallinckrodt incorporates by reference herein the discussion of harm set forth in its Memorandum in Support of Motion for Temporary Restraining Order and supporting exhibits and declarations.

[11] The government cites no authority to support its assertion that the Court should balance Mallinckrodt's hardship against the hardship the government would allegedly suffer from prompt judicial review. Gov't Br. at 17-18. The question is whether *withholding* review creates hardship. Where, as here, the issues are fit for judicial review, and there is hardship to the plaintiff from withholding review, hardship to the government is irrelevant.

Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993)), and draw "all reasonable factual inferences from [the complaint] in the plaintiff's favor.'" *F.T.C.*, 654 F. Supp. 2d at 384-85 (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999)). The Court is not bound to accept as true any legal conclusions in the complaint (*Papasan v. Allain*, 478 U.S. 265, 286 (1986)), "or 'allegations that are mere conclusions, unwarranted deductions of fact, or unreasonable inferences.'" *Kajime Constr. Servs., Inc. v. Travelers Indem. Co. of Conn.*, 782 F. Supp. 2d 167, 169-70 (D. Md. 2011) (quoting *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002)) (internal brackets omitted). A complaint should not be dismissed if it contains "'sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Vance v. CHF Int'l*, 914 F. Supp. 2d 669, 677 (D. Md. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Applying these standards, the Court should deny the motion to dismiss under Rule 12(b)(6).

1. The Court Should Deny the Motion to Dismiss Counts I and III Through V, Because the Reclassification Action is a Final Agency Action

The presumption favoring judicial review of agency actions, discussed *supra* at 13, is embodied in the APA, which covers a "broad spectrum of administrative actions" with "'generous review provisions'" that courts must give a "'hospitable interpretation.'" *Abbott Labs.*, 387 U.S. at 140-41 (quoting *Shaughnessy v. Pedreiro*, 349 U.S. 48, 51 (1955)). One such provision is the APA right to judicial review for "final agency action

for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Counts I and III through V of the complaint seek review of final agency action under the APA.[12] The Court should deny the motion to dismiss as to Counts I and III through V, because their allegations regarding final agency action easily meet the Rule 8 pleading standard.[13]

The Supreme Court has established a two-part test for "final agency action," the first of which requires that "the action must mark the 'consummation' of the agency's

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[12] The remaining count in the complaint (Count II) is a direct cause of action under the Due Process Clause and is not an APA claim. Because the requirement of a "final agency action" is limited to APA claims, and Count II is a direct cause of action under the Constitution, Count II is judicially reviewable regardless of whether there is a "final agency action." *See Trudeau*, 456 F.3d at 188-89 (direct cause of action under First Amendment was judicially reviewable even though "the absence of final agency action . . . cost [plaintiff] his APA cause of action"); *see also id*. at 191-97 (reviewing pleading sufficiency of First Amendment claim, in the absence of final agency action, under Fed. R. Civ. P. 12(b)(6)). The government's Rule 12(b)(6) motion as to Count II, which addresses pleading sufficiency unrelated to the "final agency action" issue, is discussed *infra* at 30.

[13] To the extent that the Court considers materials outside the Complaint, the Court should deny the motion based on the express concession, by FDA's Acting Deputy Director for Generic Drug Policy (who also is an FDA regulatory counsel), that the Orange Book reclassification is a "final agency action." Saltarelli Decl. ¶ 20. The evidence on this point is undisputed, because the government has not provided sworn testimony to the contrary. Although government counsel dispute the concession, they were not present during the conversation, and their representation is not evidence. Gov't Br. at 16 n.5. Furthermore, while the government asserts that the concession is not binding on the agency as a *regulatory* matter (*id*.), the statement plainly is binding on the agency as an *evidentiary* matter, as an admission by an FDA employee within the scope of his employment. Fed. R. Evid. 801(d)(2)(D). Furthermore, the "final agency action" defense is waivable because it is not jurisdictional (*see supra* at 11-12), and the concession waived the defense as a legal matter.

decisionmaking process — it must not be of a merely tentative or interlocutory nature." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal citation omitted). The complaint meets this element, by claiming that the action is "final" (Compl. ¶¶ 35, 49, 57, 62, 63), that FDA effectuated the action conclusively on a specific date (November 13, 2014) (*id.* ¶¶ 26, 29), and that the action caused immediate harm (*id.* ¶¶ 30-32).[14]

The second part of the "final agency action" test requires that the action must either be "one by which 'rights or obligations have been determined,'" or one "from which 'legal consequences will flow.'" *Bennett*, 520 U.S. at 178 (quoting *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970). The complaint satisfies this element, among other things, by alleging that legal consequences harmful to Mallinckrodt flow from the reclassification action, by making it unlawful for pharmacists in many states to substitute Mallinckrodt's drug for Concerta®. Compl. ¶¶ 13, 30.[15] The discussion *supra* at 15-19 elaborates in detail on these and other state-

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[14] The complaint also meets this element with respect to the November 6, 2014 "draft guidance," by alleging that it is "final" (Compl. ¶ 56) and that it was the substantive premise for the reclassification action (*id.* ¶¶ 27, 57).

[15] The complaint also meets this element with respect to the November 6, 2014 "draft guidance," by alleging that it triggers legal consequences by setting the substantive standards used to determine whether FDA will approve an ANDA for methylphenidate hydrochloride. Compl. ¶¶ 27, 57.

Furthermore, the "draft guidance" is a "final agency action" notwithstanding its label as a non-binding "draft." The substance of the action — not the document's title or the agency's disclaimer — is what controls. FDA's action is "final" because it meets the

(Footnote cont'd on next page)

law consequences, as well as federal-law consequences, that flow from FDA's reclassification action. It therefore is not surprising that this Court has referred to the impact of an Orange Book classification in stating (albeit in *dicta*) that "it would appear that an Orange Book designation constitutes a final agency action." *Zeneca Inc. v. Shalala*, No. CIV.A. WMN-99-307, 1999 WL 728104, at *11 n.13 (D. Md. Aug. 11, 1999), *aff'd*, 213 F.3d 161 (4th Cir. 2000).[16]

Furthermore, other case law supports the conclusion that FDA's reclassification

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two conditions described above even though the agency characterizes it as a purely "informational" document with no legal effect. *See Tozzi v. U.S. Dep't of Health & Human Servs.*, 271 F.3d 301, 310 (D.C. Cir. 2001) (EPA listing of human carcinogens allegedly "'for informational purposes only'" was reviewable final agency action).

[16] In so stating, this Court distinguished an earlier decision of this Court holding that the proposed precursor to the Orange Book was not a final agency action. The Court noted that the earlier decision did not account for the "increased significance attributed to an Orange Book listing over the years since this Court decided" the earlier case. *Id.* (citing *Pharm. Mfrs Ass'n v. Kennedy*, 471 F. Supp. 1224 (D. Md. 1979)). In fact, at the time of the earlier case, the Orange Book did not even exist yet. The Orange Book arose from the fundamental transformation of the generic drug approval process that Congress enacted in 1984. *See supra* note 8.

In addition, during the colloquy at the hearing on the motion for temporary restraining order, the Court noted that the *Zeneca* case involved an initial classification in the Orange Book, whereas the present case involves a change in an initial classification. Mallinckrodt respectfully submits that this distinction is not pertinent to the "final agency action" question. Both initial actions and amendments of those initial actions are judicially reviewable under the APA if they meet the test for a "final agency action." *See, e.g., Philip Morris USA, Inc. v. Vilsack*, 736 F.3d 284 (4th Cir. 2013) (reviewing amended regulation under the APA).

action was a final agency action, even though the significant legal consequences that flow from it are obligations created by other federal agencies and the states. The Supreme Court's statement, in *Bennett v. Spear*, that a final agency action must *either* determine "rights or obligations" *or* make "legal consequences . . . flow" (520 U.S. at 177-78) means that the legal effect of the agency's action may either be direct or indirect. *See also Sackett*, 132 S. Ct. at 1371 (distinguishing "determined" "rights or obligations" from "legal consequences" that "flow"). Final agency action *can* directly determine "rights or obligations" by directly imposing legal requirements on the plaintiff. But a final agency action also can make legal consequences "flow" through a less direct relationship to the action.

For example, when assessing whether an agency action is "final" under the APA, the Supreme Court recently noted that relevant "legal consequences" may flow from a federal agency different than the agency that took the action. *Id.* at 1371-72 (addressing EPA action that caused adverse effects under Army Corps of Engineers regulation). Similarly, the D.C. Circuit's decision in *Tozzi*, 271 F.3d 301, confirms that collateral consequences triggered either under the regulations of a different federal agency, or under state law, qualify as legal consequences that meet the second part of the "final agency action" test. *Tozzi* is particularly persuasive in this case, because FDA's actions also triggered effects under the regulations of other federal agencies and under state law.

See supra at 15-19.[17]

In *Tozzi*, the Court held that a listing of carcinogens published by the Department of Health and Human Services — which had no direct regulatory effect on the plaintiffs — was reviewable largely because it triggered collateral legal obligations (regarding listed carcinogens) under the regulations of other federal agencies (i.e., OSHA and the Department of Labor) and under state law. *Id*. at 304, 310. The carcinogen list was labeled "for informational purposes only," yet the Court properly looked beyond the form to the substance and held that the list was a final agency action. *Id*. at 310. Following *Tozzi*, the Court should disregard the Orange Book's disclaimer that it is only "informational" (*see* Gov't Br. at 5) and hold that the reclassification action is a final agency action, because it triggered legal obligations under the regulations of other agencies and state law.

2. The Court Should Deny the Motion to Dismiss Counts I and II, Because Mallinckrodt Has Properly Pleaded its Due Process Claims

The government cannot credibly claim that Mallinckrodt has failed to meet the

[17] It is very significant that the government cites *no authority* holding otherwise (i.e., that collateral consequences under the regulations of other federal agencies, or under state law, do *not* qualify as legal consequences that meet the second prong of the "final agency action" test). Gov't Br. at 15. The government does cite to *Nat'l Ass'n of Home Builders v. Norton*, 415 F.3d 8, 14-16 (D.C. Cir. 2005), but that case addressed a situation in which a federal action did not trigger *any* legal consequence under state law or otherwise. *Id*. at 15.

notice pleading standards of Rule 8 when pleading the elements of its due process claims. Mallinckrodt has alleged (1) that Mallinckrodt's approved ANDA is a property right (Compl. ¶¶ 34, 41) and (2) that the reclassification action deprives Mallinckrodt of its property right without a constitutionally-required hearing (*id.* ¶¶ 36, 43).

On the first element, the government mischaracterizes the complaint, asserting that the claimed property right is a right in the *Orange Book rating*, whereas the complaint alleges instead that the property right is a right in the *ANDA approval*. The government appears to admit that the ANDA approval is a property right, just as the complaint alleges. Gov't Br. at 19.

On the second element, the government asserts that the ANDA would have to be withdrawn entirely in order for the due process clause to trigger a hearing right. *Id.* The government cites no authority for this assertion, which appears to be based on an unsupportable claim that there is no due process hearing right unless property is entirely taken away. As the discussion and case law *infra* at 35-37 explain, even partial deprivation of a property right triggers a due process hearing right. At a minimum, FDA has partially deprived Mallinckrodt of a property right by impairing its ANDA approval through the reclassification action (even though FDA has not formally withdrawn the approval). The Court should deny the motion to dismiss Counts I and II.

II. THE COURT SHOULD GRANT MALLINCKRODT'S MOTION FOR SUMMARY JUDGMENT

A. FDA Acted Unlawfully By Effectively Taking the Drug Off the Market Without Providing Mallinckrodt With a Hearing Where it Could Defend the Product

The effect of FDA's reclassification action cannot be overstated — it will lead to the removal of Mallinckrodt's generic methylphenidate ER product from the U.S. market. Prohibiting generic substitutions effectively takes the drug off the market, because pharmacists will not substitute the drug in filling brand-name prescriptions, and Mallinckrodt's distributor customers will not buy it. *See generally* Kaczmarek Decl. The Court should grant Mallinckrodt's motion for summary judgment as to Counts I-III, because FDA is effectively taking the drug off the market without providing Mallinckrodt with a hearing.[18]

1. The Court Should Grant Mallinckrodt Summary Judgment on Count III, Because FDA Exceeded its Statutory Authority By Effectively Taking the Drug Off the Market Without Providing Mallinckrodt With a Hearing

FDA exceeded its statutory authority by effectively taking the drug off the market without providing Mallinckrodt with a hearing. The FFDCA provides only ***one*** mechanism for taking a generic drug off the market: withdrawing (or suspending)

[18] The removal from the market is occurring over time and is not yet complete as of the time of the filing of this Memorandum. That does not mean that either the purpose or ultimate effect of FDA's reclassification action differs from an action formally withdrawing Mallinckrodt's ANDA approval.

ANDA approval under 21 U.S.C. § 355(e). *See supra* at 6. Section 355(e) requires that the drug's sponsor is entitled to "due notice and opportunity for hearing" *before* FDA can withdraw the ANDA approval. 21 U.S.C. § 355(e). FDA's regulations provide the specific procedures for the statutorily-required hearing. *See* 21 C.F.R. § 314.150; 21 C.F.R. pt. 12.[19]

FDA has no statutory authority to take a drug off the market through other actions not specified in section 355(e). *See Cal. Canners & Growers Ass'n v. United States*, 7 Cl. Ct. 69, 88 (1984) (FDA had no statutory authority to remove drugs from the market through an immediately-effective regulation and was required to follow the hearing process specified in 21 U.S.C. § 355(e)). That conclusion flows directly from a recent D.C. Circuit decision construing the parallel statutory requirements governing FDA's authority to remove a medical device from the market (following an earlier FDA decision that authorized marketing the device). In *Ivy Sports Medicine, LLC v. Burwell*, 767 F.3d 81 (D.C. Cir 2014), *pet. for reh'g en banc filed* (Nov. 10, 2014), the D.C. Circuit held that to remove the medical device at issue from the market, FDA must follow a

[19] There is a narrow exception to the advance hearing requirement under circumstances in which — unlike this case — there is "an imminent hazard to the public health." 21 U.S.C. § 355(e). Under those unusual circumstances, the Secretary of the Department of Health and Human Services (in an action that "shall not be delegated" to any subordinate official) can immediately suspend the approval of an ANDA without first holding a hearing — but the sponsor is *still* entitled to "prompt notice" and the "opportunity for an expedited hearing" shortly after the suspension occurs. *Id.*

statutorily-prescribed notice and comment procedure and could not "achieve the same result" through a different reconsideration process not mentioned in the statute. *Id.* at 87. The reason is that when Congress expressly provides a mechanism for FDA to reconsider and reverse an earlier premarket clearance decision, Congress "displace[s]" FDA's authority to reconsider and reverse such a decision through actions not specified in the statute. *Id.* at 86; *see also id.* ("any inherent reconsideration authority does not apply in cases where Congress has spoken").

FDA has exceeded its statutory authority by effectively taking Mallinckrodt's methylphenidate ER off the market through other actions not specified in section 355(e). On information and belief, FDA has reclassified the drug with a "BX" code for the express purpose of removing it from the market. The ultimate effect is the same as withdrawing the drug's ANDA approval. *See supra* at 31. As in *Ivy Sports Medicine*, FDA had no statutory authority to "short-circuit [the] statutory process" for removing Mallinckrodt's drug from the market by taking a different type of action to "achieve that same result." 767 F.3d at 87.

In addition, as in *Ivy Sports Medicine*, the fact that the statutory process is slower and more deliberative than an extra-statutory process is a virtue, not a vice. In *Ivy Sports Medicine*, the D.C. Circuit addressed FDA's view that notice and comment (regarding removing a medical device from the market) was unnecessary — a view the court called "a not-uncommon sentiment among agencies that want to take action more promptly."

767 F.3d at 87. The court explained that "notice and comment helps to prevent mistakes, because agencies receive more input and information before they make a final decision." *Id*. The court further explained that "notice and comment also helps ensure that regulated parties receive fair treatment, a value basic to American administrative law." *Id*. at 87-88. These concepts apply with equal force in this case. The section 355(e) hearing procedures help prevent FDA mistakes and also ensure that parties such as Mallinckrodt receive the fair treatment that Congress intended them to have when FDA considers removing their drugs from the market. The Court should grant summary judgment for Mallinckrodt on Count III.

2. The Court Should Grant Mallinckrodt Summary Judgment on Counts I and II, Because FDA Violated Mallinckrodt's Fifth Amendment Due Process Rights By Impairing the Company's Property Right in its Drug Approval Without Providing Mallinckrodt With a Hearing

The statutory hearing rights described above derive from an underlying constitutional right to notice and a hearing guaranteed by the Fifth Amendment's Due Process Clause. FDA violated the company's due process rights by effectively taking its generic methylphenidate ER off the market without providing Mallinckrodt with a hearing.

Minimum due process requirements include notice and an opportunity for a hearing. *See, e.g*., *Propert v. D.C.*, 948 F.2d 1327, 1331 (D.C. Cir. 1991) (citing *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 433 (1982)). Among other things, the due process clause bars the government from modifying, suspending, revoking, or

withdrawing a private party's property right without an opportunity to be heard "at a meaningful time and in a meaningful manner." *See, e.g.*, *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (citation omitted); *Bell v. Burson*, 402 U.S. 535, 539 (1971). As FDA's own regulations recognize, Mallinckrodt's approved ANDA is such a property right. *See, e.g.*, 21 C.F.R. § 314.72 (describing ANDA as an interest that is "owne[d]" and indicating that "rights to the application" can be "transferred to [a] new owner").

When FDA approves an ANDA, it grants the ANDA sponsor permission to market its drug lawfully in interstate commerce. *See* 21 U.S.C. § 355(a) (marketing in interstate commerce prohibited until approval occurs); 21 C.F.R. § 314.105(d) (same). It is well settled that such a government-issued permit or license is a property interest protected by the Due Process Clause. *See, e.g.*, *Barry v. Barchi*, 443 U.S. 55 (1979); *Richardson v. Town of Eastover*, 922 F.2d 1152, 1156 (4th Cir. 1991) (license issued by the government that can be suspended or revoked only upon a showing of cause creates a property interest protected by constitutional due process); *Scott v. Williams*, 924 F.2d 56, 58 (4th Cir. 1991) (citing *Burson*, 402 U.S. at 539); *Ihnken v. Gardner*, 927 F. Supp. 2d 227, 237 (D. Md. 2013) (citing *Richardson* with approval); *U.S. ex rel. Joslin v. Cmty. Home Health of Md., Inc.*, 984 F. Supp. 374, 379 (D. Md. 1997) ("[C]ourts have uniformly held that the holder of a license has a property right protected by the appropriate Federal Due Process Clause."); *see also* Donald O. Beers & Kurt R. Karst, Generic and Innovator Drugs: a guide to FDA approval requirements § 3.04 (8th ed.

2013) ("It seems clear that the approval of an [ANDA], an approval of considerable financial value in many instances, would be considered a property right in the due process context.").

When it reclassified Mallinckrodt's methylphenidate ER, FDA eviscerated the company's property right in its ANDA by effectively taking the drug off the market. But to find a due process violation, the Court need not even agree that the drug was effectively taken off the market, as long as the Court concludes that Mallinckrodt's property right has been at least partially impaired (which it quite obviously has been). FDA had no constitutional authority to impair Mallinckrodt's property right to *any* extent (even partially) without giving Mallinckrodt notice and an opportunity to be heard.[20] The

[20] *See, e.g.*, *Goss v. Lopez*, 419 U.S. 565, 576 (1975) ("The Court's view has been that as long as a property deprivation is not *de minimis*, its gravity is irrelevant to the question whether account must be taken of the Due Process Clause.") (citing *Sniadach v. Family Fin. Corp. of Bay View*, 395 U.S. 337, 342 (1969) (Harlan, J., concurring)); *Boddie v. Connecticut*, 401 U.S. 371, 378-79 (1971); *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 570 n.8, (1972)); *Fuentes v. Shevin*, 407 U.S. 67, 90 n.21 (1972); *Connecticut v. Doehr*, 501 U.S. 1, 12 (1991) (even "temporary or partial impairments to property rights" are sufficient to merit due process protection); *Garraghty v. Jordan*, 830 F.2d 1295, 1299 (4th Cir. 1987) ("the length and consequent severity of a deprivation . . . 'is not decisive of the basic right' to a hearing of some kind." (quoting *Goss*, 419 U.S. at 576)); *Morrash v. Strobel*, 842 F.2d 64, 68-69 (4th Cir. 1987) (recognizing that impairment of liberty interest merits due process protection); *Weathersbee v. Baltimore City Fire Dep't*, 970 F. Supp. 2d 418, 435-36 (D. Md. 2013); *see also Cobb v. Saturn Land Co.*, 966 F.2d 1334, 1336 (10th Cir. 1992) (dismissal of the plaintiff's claim "[could] not be affirmed on the basis that the incomplete or partial deprivation involved did not implicate due process guarantees"); *Nat'l Ass'n of Radiation Survivors v. Walters*, 589 F. Supp. 1302, 1312 (N.D. Cal. 1984), *rev'd on other grounds*,

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Court therefore should grant summary judgment for Mallinckrodt on Counts I and II.

B. The Court Should Grant Mallinckrodt Summary Judgment on Count III, Because FDA Has Not Satisfied the Statutory Evidentiary Standard Necessary to Take a Drug Off the Market

FDA also has exceeded its statutory authority, because it has effectively taken a drug off the market without satisfying the evidentiary standard of 21 U.S.C. § 355(e). Under section 355(e) — which as explained above establishes the only mechanism for taking a generic drug off the market — there are specific evidentiary standards that FDA must satisfy to justify its action. FDA only has statutory authority to take a drug off the market for lack of effectiveness if "there is a *lack of substantial evidence* that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 355(e)(3) (emphasis added). FDA cannot meet this statutory standard.

The administrative law substantial evidence standard is well established. Courts have defined it to mean "'more than a scintilla, but . . . something less than a preponderance of the evidence.'" *Minisink Residents for Envtl. Pres. & Safety v. FERC*, 762 F.3d 97, 108 (D.C. Cir. 2014) (quoting *FPL Energy Me. Hydro LLC v. FERC*, 287 F.3d 1151, 1160 (D.C. Cir. 2002); *see also SEC v. FLRA*, 568 F.3d 990, 995 (D.C. Cir.

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473 U.S. 305 (1985) (recognizing "total or partial termination" of property interest as warranting due process).

2009) (substantial evidence is "'something less than the weight of the evidence'") (citation omitted). The most that FDA can purport to show here — a mere "'possibility of drawing . . . inconsistent conclusions from the evidence'" — does *not* mean that there is a lack of substantial evidence. *Id.* (quoting *Consolo v. Fed. Maritime Comm'n*, 383 U.S. 607, 620 (1966). For FDA to establish a *lack* of substantial evidence under section 355(e)(3), FDA would need to show that the evidence of effectiveness is *substantially* less than a preponderance of the evidence (and perhaps only a "scintilla"). *See Minisink Residents*, 762 F.3d at 108.

FDA does not even attempt to assert that it has reclassified Mallinckrodt's methylphenidate ER because of such minimal evidence of effectiveness. FDA set forth its rationale for the reclassification decision in a 15-page memorandum provided to Mallinckrodt after FDA advised the company of the reclassification. In that memorandum, FDA concluded merely that it "has *reason to believe* that the Mallinckrodt products *may not* be therapeutically equivalent to Concerta." Saltarelli Decl. ¶ 25, Ex. D at 14 (emphasis added). In a related press release, FDA was even more equivocal, asserting: "FDA has concerns about whether or not" Mallinckrodt's product is therapeutically equivalent. Saltarelli Decl. Ex. B. FDA acknowledged that its "concerns" relate only to "some patients," and FDA emphasized that "the total number of lack of effect reports . . . is *very small* compared to the overall usage of the products." *Id.*, Ex. C (emphasis added). Therefore FDA advised that patients currently taking Mallinckrodt's

product "should not make changes to their treatment." *Id.*, Ex. B.

Of course, the statute does not permit FDA to take a generic drug off the market based on "concerns" about "whether or not" the drug is therapeutically equivalent for "some patients." And even assuming FDA's analysis of adverse event reports were valid, *but see infra*, even FDA acknowledges Mallinckrodt's product has proven to be effective for all but "a very small" number of patients. Thus, by FDA's own admission, there is more than substantial evidence that Mallinckrodt's product is therapeutically equivalent. The agency therefore has not met the evidentiary standard in the statute for removing the product from the market. The Court should grant summary judgment for Mallinckrodt on Count III.

C. The Court Should Grant Summary Judgment for Mallinckrodt on Count V, Because FDA's Reclassification Action is Arbitrary and Capricious

The Court should grant summary judgment for Mallinckrodt on Count V, because FDA's reclassification action is arbitrary and capricious for the reasons explained below.

1. FDA's Reclassification Action is Arbitrary and Capricious Because FDA Has Not Even Satisfied its Own Standard for Reclassification Set Forth in the Orange Book

FDA's reclassification action is arbitrary and capricious, because FDA has not even satisfied its own standard for reclassification stated in the Orange Book. The Orange Book includes FDA's internal procedural rules for classifying drugs according to their therapeutic equivalence. Those rules define the different classifications at least in part by reference to the data pertinent to a drug's therapeutic equivalence. The Orange

Book defines the BX classification at issue here as "drug products for which the data that have been reviewed by the Agency are *insufficient to determine therapeutic equivalence* under the policies stated in [the Orange Book]." Ex. 1 at xx (emphasis added). However, in its reclassification decision rationale, FDA does not even attempt to suggest that the data meet this "insufficiency" standard.

Instead, FDA asserts simply that it "has *reason to believe* that the Mallinckrodt products *may not be* therapeutically equivalent to Concerta." Saltarelli Decl. Ex. D at 14 (emphasis added). That equivocal statement falls far short of a determination that therapeutic equivalence data "*are* insufficient" — which is the standard set forth for the classification BX in the Orange Book. Because FDA failed to follow its own definitional standard set forth in the procedural rules of the Orange Book, the agency's reclassification action is arbitrary and capricious. *See, e.g.*, *D&F Afonso Realty Trust v. Garvey*, 216 F.3d 1191, 1196 (D.C. Cir. 2000) (an agency acts arbitrarily and capriciously when it "act[s] contrary to its own procedure"); *see also Town of Barnstable, Mass. v. FAA*, 659 F.3d 28, 36 (D.C. Cir. 2011) (standard of reasoned decisionmaking not satisfied when agency "abandon[ed] its own established procedure").

2. FDA's Reclassification Action is Arbitrary and Capricious Because FDA Has Not Satisfied Applicable Requirements for Reasoned Decisionmaking

FDA's reclassification action also is arbitrary and capricious, because the agency's stated justification for the reclassification is "not sufficient to enable [the Court] to conclude" that the action "was the product of reasoned decisionmaking." *Motor Vehicle*

Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 52 (1983). "The importance of reasoned decisionmaking in an agency action cannot be over-emphasized. When an agency . . . is vested with discretion to impose restrictions on an entity's freedom to conduct its business, the agency must exercise that discretion in a well-reasoned, consistent, and evenhanded manner." *Greyhound Corp. v. ICC*, 668 F.2d 1354, 1359 (D.C. Cir. 1981). This requirement for reasoned decisionmaking is properly enforced through judicial review regardless of whether the agency's action involves scientific matters within the agency's sphere of expertise. *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1145 (D.C. Cir. 2013), *reh'g en banc denied* (Oct. 24, 2013).

The 15-page memorandum described above is FDA's only proffered explanation for its action, and it contains numerous glaring errors that demonstrate the action was arbitrary and capricious.[21] *First*, FDA "relied on a selection of data, tests, and standards that did not always appear to be logical, obvious, or even rational." *See Dow AgroSciences*, 707 F.3d at 475. Most notably, FDA relied on a collection of adverse event reports to support its decision. But FDA's own analysis shows that *most* of the cited reports were about *other* products — i.e., reports of efficacy concerns about drugs *other*

[21] That memorandum is part of the administrative record, because it states "the reasons given by the agency for taking the action." *Dow Agrosciences*, 707 F.3d at 467.

than Mallinckrodt's methylphenidate ER. Saltarelli Decl. ¶¶ 28-31.[22] FDA cannot rationally use reports about other products to support a therapeutic equivalence determination about Mallinckrodt's product.

Second, the agency treated *all* "lack-of-effect" complaints concerning Mallinckrodt's drug — regardless of the factual scenario in which the complaints arose — as evidence of lack of therapeutic equivalence. Saltarelli Decl. ¶¶ 33-35. Common sense establishes that not all "lack-of-effect" complaints are evidence of lack of therapeutic equivalence between a brand drug and generic. In fact, *most* reporting scenarios are irrelevant to the issue of therapeutic equivalence between a brand drug and generic, because most do not involve a patient switching medication from the brand drug to the generic — the only scenario relevant to therapeutic equivalence. *Id*. Reports that arise in other scenarios — *e.g.*, patients who never took the brand drug but are taking the generic in the first instance and patients who are being co-administered medications that impact efficacy — provide no rational or logical support for any conclusions as to the therapeutic equivalence of Mallinckrodt's product. *Id*.[23] Here FDA lumped all "lack-of-

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[22] The government's memorandum opposing the motion for temporary restraining order concedes this point. *See* Def.'s Mem. in Opp'n to Pl.'s Mot. for TRO ("Gov't TRO Br."), ECF No. 25, at 18-19 ("Mallinckrodt criticizes the agency's reliance on adverse event reports relating to other products, but it does not dispute that the agency also relied on adverse event reports relating to *Mallinckrodt's* products.").

[23] The government's memorandum opposing the motion for temporary restraining order concedes that FDA relied on lack-of-effect complaints that do not relate to

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effect" complaints together, piled them on top of a mountain of reports about other products, and used this "data" as the foundation upon which to build its reclassification action. Because FDA "relie[d] on one unsubstantiated conclusion heaped on top of another," its action was arbitrary and capricious. *See Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014).

Third, even assuming *arguendo* that all lack-of-effect complaints concerning Mallinckrodt's drug were relevant, FDA did not compare them to analogous complaints concerning Concerta®. Mallinckrodt's analysis of the adverse event reports relied upon by FDA (a portion of the administrative record that is publicly available) demonstrates that the brand-name drug Concerta® has a *much higher* rate of lack-of-effect complaints than Mallinckrodt's drug. Supplemental Decl. of Mario Saltarelli ¶¶ 6-9. In its memorandum justifying its reclassification action, FDA did not even acknowledge data about adverse events for Concerta®. Without assessing comparative adverse event reports about Concerta®, FDA could not rationally rely on adverse event reports about Mallinckrodt's drug to conclude that it is not therapeutically equivalent to Concerta®. This glaring omission alone renders FDA's action arbitrary and capricious.

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therapeutic equivalence. Gov't TRO Br. at 19 ("Mallinckrodt complains that 'FDA considered "lack-of-effect" complaints that do not relate to therapeutic equivalence . . . but again, Mallinckrodt does not dispute that FDA considered "lack-of-effect" complaints that *are* evidence of therapeutic equivalence.'").

Fourth, FDA also relied on plainly inaccurate facts. FDA claimed, for example, that there was a "spike" in reported events for methylphenidate products in April 2013, and the agency speculated that this spike "may be attributable to the launch of [Mallinckrodt's] product," because, according to FDA, "the 1st marketing of the Mallinckrodt product was 3/25/2013." Saltarelli Decl. ¶ 32. But FDA's premise is simply false. As FDA's own memo states, Mallinckrodt's ANDA "was approved on 12/28/2012," and thus Mallinckrodt first began marketing and selling one strength of its product (27 mg strength) in December 2012 — more than three months before the alleged "spike." *Id.*[24] FDA's speculative conclusion that the "spike" was caused by Mallinckrodt's initial entry into the market is just one example of FDA "offer[ing] an explanation for its decision that runs counter to the evidence before [it]." *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

Fifth, beyond the agency's irrational and illogical use of reporting "data," FDA also relied on a fundamentally flawed and scientifically unsupported methodology for predicting therapeutic equivalence. Specifically, FDA attempted to predict clinical effects based on the plasma concentration levels of Mallinckrodt's product. Saltarelli

[24] The government's memorandum opposing the motion for temporary restraining order concedes that FDA relied on the wrong date. Gov't TRO Br. at 19 ("Mallinckrodt notes that the agency identified the wrong date by which *one* of its products entered the market, but leaves untouched the relevant part of the agency's comment — that the spike of adverse event reports in April may be attributable to Mallinckrodt's product.").

Decl. ¶¶ 36-43. FDA's modeling approach was based on the assumption that there is a direct and quantitative correlation between plasma concentration and clinical effects of methylphenidate. *Id.* ¶ 40. By FDA's own admission, this is "the first time such modeling has been used" to support a therapeutic equivalence decision. *See id.*, Ex. D at 8. FDA also has publicly emphasized that "there is no authoritative literature information on the correlation of dose or plasma concentration with clinical effects of methylphenidate." *See id.* ¶ 41. The government's memorandum opposing the motion for temporary restraining order also concedes that no such authoritative literature exists, and even admits that FDA has simply assumed this key premise for its conclusions:

> The agency's public statement that there is a lack of 'authoritative literature information on the correlation of dose or plasma concentration with clinical effects of methylphenidate' does not mean that there is *no* correlation between concentration and clinical effects, so FDA's statement was wholly consistent with its use of a modeling approach that assumes a correlation exists.

Gov't TRO Br. at 19. FDA cannot rationally rely on a new and untested method that is based on assumptions not supported by existing science. *Cf. Nat'l Ass'n of Clean Water Agencies*, 734 F.3d at 1145 ("We are hesitant to rubber-stamp EPA's invocation of statistics without some explanation of the underlying principles or reasons why its formulas would produce an accurate result, particularly when the [known data] . . .

demonstrate flaws in the formula.").[25]

Finally, FDA failed to consider or even acknowledge a host of relevant data that contradict the agency's conclusions. For example, FDA had in its possession *actual* data showing the Mallinckrodt product's clinical effects. Saltarelli Decl. ¶¶ 44-46. It appears the agency never utilized this data — and failed even to acknowledge its existence — but instead opted to *predict* the same information using the untested method described above. *Id*. In other words, FDA ignored actual data in favor of flawed, speculative guesses. Similarly, FDA ignored data in its possession that directly conflict with the agency's speculative assertion that there are "concerns of possible in vivo [active drug ingredient] degradation." *Id*. ¶¶ 47-50. Of course, "an agency's refusal to consider evidence bearing on the issue before it constitutes arbitrary action within the meaning of § 706," and "an agency cannot ignore evidence contradicting its position." *Butte Cnty. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010)*; accord Sorenson Commc'ns Inc. v. FCC*, 755 F.3d at 710 (rejecting agency action where "there was contrary evidence" but agency "left th[o]se serious concerns unaddressed"). The Court should grant summary judgment for

[25] The "draft guidance" upon which the reclassification decision relies rests on the same flawed assumption that plasma concentration levels predict clinical effects. Mallinckrodt's public comments on the "draft guidance," attached as Attachment A, describe the flaw in detail. The Court should take judicial notice of this public record and conclude, based on the analysis set forth therein, that the "draft guidance" is arbitrary and capricious, because it is based on flawed and speculative assumptions. Because the reclassification action relied on the "draft guidance," the reclassification action also is arbitrary and capricious.

Mallinckrodt on Count V.

D. The Court Should Grant Summary Judgment for Mallinckrodt on Count IV, Because FDA Has Violated Notice and Comment Rulemaking Requirements

FDA has informed Mallinckrodt that a major premise for the reclassification action is that Mallinckrodt's methylphenidate ER tablets did not satisfy FDA's new "draft guidance" (for bioequivalence regarding methylphenidate hydrochloride) issued on November 6, 2014. *See* Saltarelli Decl. ¶ 19. FDA's reclassification action is invalid, because the "draft guidance" underlying that action violates notice and comment rulemaking requirements imposed by the APA. The Court therefore should grant summary judgment for Mallinckrodt on Count IV.[26]

[26] Contradicting FDA's prior statement to Mallinckrodt, the government now asserts that FDA did not rely on the draft guidance as a basis for the reclassification decision. Gov't Br. at 18 n.6. The government is splitting hairs here, given that it appears to acknowledge that FDA *did* apply the *methodology* stated in the draft guidance as the substantive standard for decision. *Id*. The government is attempting to draw a fine distinction between the *substance* of the rule/methodology it has applied and the hard-copy *document* (i.e., draft guidance) in which the agency publicly announced that rule/methodology. Mallinckrodt's claim does not turn on such a superficial distinction between form and substance. Regardless of when (or whether) the rule/methodology was memorialized in writing and publicly announced, FDA violated APA requirements when it adopted and applied the methodology without notice and comment.

Furthermore, to the extent that the government could establish that the reclassification action was not based even on the *substance* of the draft guidance's methodology, the action was arbitrary and capricious. FDA's decisional memorandum makes clear that FDA did not rely on the methodology announced in FDA's original 2012 draft guidance (under which the agency approved Mallinckrodt's ANDA), which was superseded by the November 6, 2014 draft guidance. Saltarelli Decl., Ex. D at 9-11.

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The APA requires an agency to follow notice and comment requirements in promulgating a "legislative" rule, unless "the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B); *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1108-09 (D.C. Cir. 1993). FDA violated 5 U.S.C. § 553, because the "draft notice" is a "legislative" rule, and the agency neither satisfied notice and comment requirements nor published findings establishing a "good cause" exemption.[27]

As Mallinckrodt has now learned to its detriment, the new "draft guidance" sets forth the substantive scientific standards under which FDA will — or will not — find methylphenidate hydrochloride drugs bioequivalent (and therefore approvable through an ANDA). The "draft guidance" meets the Administrative Procedure Act's definition of a "rule," because it is an "agency statement of general or particular applicability and future

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If the agency abandoned the original methodology and really did not rely on the new methodology addressed in the November 6 draft guidance, there is no basis for understanding which methodology FDA *did* rely upon. An agency action fails to satisfy APA requirements for rational decision making, and therefore is arbitrary and capricious, when the Court "cannot discern precisely what the [agency's] decisional standard was." *Select Specialty Hosp.-Bloomington v. Burwell*, 757 F.3d 308, 314 (D.C. Cir. 2014).

[27] FDA did initiate a notice and comment process for the "draft guidance." But the process was incomplete at the time FDA applied the "draft guidance" to Mallinckrodt; the comment period remained open until January 5, 2015. 79 Fed. Reg. 65,978 (Nov. 6, 2014).

effect designed to implement . . . or prescribe law or policy. . . . ." 5 U.S.C. § 551(4). And the "draft guidance" also is a "legislative" rule, because it "*modifies* or *adds* to a legal norm based on the agency's *own authority*" and thereby "really adds content to the governing legal norms." *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95, 96 (D.C. Cir. 1997) (emphasis in original). The "draft guidance" adds content to the governing legal norms by changing the substantive criteria under which FDA will permit a drug to be marketed. In this case, the "draft guidance" provided the substantive basis for FDA's determination that methylphenidate ER may not be bioequivalent or therapeutically equivalent to Concerta®. Such an "agency action that sets forth legally binding requirements for a private party to obtain a permit or license is a legislative rule." *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251-52 (D.C. Cir. 2014).[28]

Furthermore, FDA's characterization of its legislative rule as a *non-binding* "draft guidance" or "recommendation" does not undermine the conclusion that it is a legislative rule. It is well established that it is the *substance* of the rule that controls whether a rule is legislative: "the agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the 'force of law,' but the record

[28] It is notable that in the Orange Book, FDA acknowledges that notice and comment is required "before making a change in a therapeutic equivalence code for an entire category of drugs." Ex. 1 at xxii. Here the "draft notice" was the basis for changing the code for the only two non-authorized generic manufacturers in the methylphenidate hydrochloride extended release category. *See* Kaczmarek Decl. ¶¶ 40, 56.

indicates otherwise." *CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003). Courts therefore have not hesitated to invalidate agency pronouncements labeled as non-binding "guidances" where, as here, they actually are operating as legislative rules. *See, e.g.*, *Syncor*, 127 F.3d at 93, 96 (notice characterized by FDA as a "guidance" was legislative rule subject to notice and comment requirements); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023, 1028 (D.C. Cir. 2000) (EPA "guidance" document was legislative rule subject to notice and comment requirements notwithstanding "boilerplate" disclaimer that "'[t]he policies set forth in this paper are intended solely as guidance, do not represent final Agency action, and cannot be relied upon to create any rights enforceable by any party.'") (citation omitted); *Natural Res. Def. Council v. EPA*, 643 F.3d 311, 320-21 (D.C. Cir. 2011) (EPA "guidance" was legislative rule).

CONCLUSION

The Court should deny the government's motion to dismiss and grant Mallinckrodt's motion for summary judgment.

Respectfully submitted,

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January 9, 2015